510(k) Summary

Prepared on December 13, 2002

K024124

This 510(k) Summary is submitted in accordance with 21 CFR 807.92.

MAR 1 4 2003

Trade Name: UF500 Circuit with In-line Needleless Access Port

Manufacturer:
Chf Solutions, Inc.
Suite 170 – 7601 Northland Drive
Brooklyn Park, MN 55428

Official Contact:
Amy Peterson
Vice President, RA/QA/CR
Telephone: 763-463-4620 Fax: 763-463-4606

Device Generic Name: Blood Filter Circuit

Classification:

System 100 (Primary Classification)	Needleless Access Port feature
• Class: II (21 CFR 876.5860)	• Class: II (21 CFR 880.5440)
• Panel: Gastroenterology-Urology	• Panel: General Hospital
• Product code: KDI	• Product code: FPA

Predicate Devices:

• CHF Solutions, System 100 (K013733)	• B. Braun Medical Inc. (K955585)

Device Description: The modified/alternate UF500 circuit incorporates an in-line needleless valve on the circuit withdrawal, infusion or both tubing lines. The in-line needless valve is independently commercially available medical device cleared for commercial distribution since May 15, 1996 (K955585) known as the ULTRASITE® valve. This is a luer activated valve manufactured and distributed by B. Braun Medical. CHF Solutions, Inc. is placing this valve at the end of a short piece of tubing (extension arm) that is permanently joined to the A1500 circuit of the System 100 (K013733) with a tee connector. A sliding clamp is also included on the extension arm and is blue on the withdrawal side and white on the infusion side. The in-line needleless access port allows the health care provided access to the circuit/vasculature without disconnecting the catheter connections or catheter extension (when used) for aspiration, injection, or gravity flow of fluids.

Indication for Use:

- For use with the System 100.
- For aspiration, injection, or gravity flow of fluids using a male luer fitting.

Safety & Performance: The modified/alternate UF500 circuit with an in-line needleless access port and predicate devices are identical in materials of construction, packaging and sterilization. The modified/alternative UF500 circuit is provided sterile and nonpyrogenic. Bench tests demonstrate the modified/alternative UF500 is remains compatible with the System 100.

Conclusion: Based on the intended use, technology characteristics and bench testing, the modified/alternative UF500 circuit has been shown to be safe and effective for its intended use. This product is substantially equivalent[2] and considered acceptable for the intended use.

[2] This document uses the term "substantial equivalent" as intended in 21 CFR 807.87 and not as defined in Title 36 of the U.S. Code.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 4 2003

Ms. Amy Peterson
Vice President RA/QA/CR
CHF Solutions, Inc.
Suite 170-7601 Northland Drive
BROOKLYN PARK MN 55428

Re: K024124
Trade/Device Name: UF500 with Needleless Access Port
Regulation Number: 21 CFR 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: 78 KDI
Dated: December 13, 2002
Received: December 16, 2002

Dear Ms. Peterson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if know): __K024124_____

Device Name: UF500 with Needleless Access Port

FDA's Statement of the Indication For Use for device:

For use with the System 100. The System 100 is indicated for temporary (up to eight hours) ultrafiltration treatment of patients with fluid overload.

The UF500 blood circuit with needleless access port allows for aspiration, injection, or gravity flow of fluids using a male luer fitting.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K024124